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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,585	08/28/2003	Diane Thibault	13/082-1-D1	7451
28513	7590	09/24/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,585

Applicant(s)

THIBEAULT ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 5 is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/20/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 is broader in scope than parent claim 3, not more limited.

Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The intended scope of claim 2 is not clear. The claim states in the preamble "consisting of a truncation", which is closed in scope, but later recites "has the minimal amino acid sequence from residues 904 to 1206...". "Minimal" appears to open the scope. Is the intent a polypeptide that consists of residues 904 to 1206 of the recited strain, or is the intent a polypeptide that includes at least 904-1206 but does not include the full-length protease? Also, it is not clear what is the sequence of "the HCV1b-40 full-length NS2/3 protease."

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim requires a truncated sequence from HCV 1b-40 HCV, and does not describe

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a reproducible method to obtain HCV 1b-40. Therefore practice of this invention requires access to at least this segment of HCV 1b-40. This claim may be enabled by deposit of the biological material HCV 1b-40, or by amending the claim to recite the specific sequence of the claimed segment of HCV 1b-40 (if the sequence is disclosed in the specification).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pieroni et al (Journal of Virology 71: 6373-6380, 1997) or Reed et al (Journal of Virology 69:4127-4136, 1995) or Drake et al (Journal of Biological Chemistry 274:34511-34514, 1999). Claim 1 is drawn to an "isolated polypeptide," and specification page 10 defines this term as "enriched with respect to cellular components". Since it is not at all clear how this definition applies to proteins made acellularly, the broadest reasonable meaning of "isolated" is used in interpreting the claims. Pieroni and Drake both teach a full-length NS2/3 protein which is isolated by virtue of its acellular synthesis, see for example Figure 1 of either Pieroni or Drake. Reed teaches truncated NS2/3 proteins which are enriched with respect to cellular components by virtue of extraction and immunoprecipitation, see page 4128 under "expression and analysis of HCV proteins" and figures 2-4. Therefore each reference meets each and every limitation of this claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pieroni et al (Journal of Virology 71: 6373-6380, 1997) or Reed et al (Journal of Virology 69:4127-4136, 1995). Pieroni teaches an isolated truncated NS2/3 protease protein containing residues 849-1325, see for example Figure 1, part B, lanes 19-21. This protein necessarily has residues 904-1206. Reed teaches a variety of isolated truncated NS2/3 proteases. However, the claim recites sequence from HCV strain 1b-40, and neither reference identifies the HCV sequence as obtained from strain 1b-40. Since neither the specification nor the references appear to disclose the actual structure of the polypeptide, the examiner

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cannot determine whether or not the sequences are identical. If they are identical, then one or the other reference anticipates the invention as claimed; if they are not identical, then the claimed invention is an obvious variant, since it would be obvious to make the same or similar fragment from any HCV strain. Therefore the invention as a whole is prima facie obvious, if not anticipated.

Allowable Subject Matter

Claims 3 and 5 are allowed.

Claims 3-5 are free of the art, because the prior art does not teach SEQ ID NO: 4, 10-15 or sequences 90% identical to SEQ: 4 or 10, nor provide motivation to alter known sequences to arrive at these particular structures.

Steinkuhler et al US 2004/0054134 is cited as of interest. This application is not available as prior art, but note the similar claims and the earlier priority date.

Information Disclosure Statement

The documents on the IDS filed 8/28/2003 have not been considered yet, because the parent application containing the documents is not complete as an image file and unobtainable as a paper file. The listed references will be considered in a future Office action if the parent application becomes available to the examiner, or if applicant provides replacement copies of the cited references.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/21/04


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